K040061

APR - 8 2004

Section D 510(k) Summary

In accordance with the requirements of SMDA 1990 and 21 CFR 807.92, this 510(k) Summary is provided:

Submitter: Medtronic MiniMed, 18000 Devonshire Street, Northridge CA 91325

Contact: Gerda Resch, Department Regulatory Affairs, (818) 576-4198, (818) 576-6273 (v/f)

Name of Device: MicroMed 407C

Predicate Device: Medtronic MiniMed Model 407C Medication Pump; and SIMS Deltec CADD-Micro, Model 5900

Description of the Device: The MicroMed 407C external pump is a syringe-reservoir, rate-programmable pump designed for infusion of medication labeled for subcutaneous and, intrathecal infusion, at set and variable rates, as prescribed by the user's physician. The 407C is restricted to sale by or on the order of a physician. It is not intended nor indicated for the delivery of blood or blood products. The principal features of the 407C Medication Pump also known as the MicroMed 407C described in this submission are:

The features of device that is the subject to this submission are identical to those of the predicate device (K991013). The only change is expansion of the indications for use to include intrathecal in fusion.

This change to the indications for use will have no untoward effect on the safety and effectiveness of the device.

Intended Use of the Device: The Medtronic MiniMed MicroMed 407C Drug Infusion Pump is indicated for infusion of medication labeled for subcutaneous and intrathecal infusion. The pump is intended for therapies at set and variable rates, for therapies including, but not limited to chemotherapy, antibiotic therapy, and controlled analgesia.

Comparison of the Technological Features of the Device and Predicate Devices: The technological features of the MicroMed 407C do not differ from the previously cleared 407C Medication Pump. The MicroMed 407C is intended for infusion of medication labeled for subcutaneous and intrathecal infusion, while the 407C Medication Pump is indicated for infusion of medication labeled for subcutaneous administration only. The CADD-Micro, Model 5900 is intended for infusion of medication labeled for subcutaneous, intravenous, intra-arterial, intraperitoneal, intrathecal space, or subarachnoid space administration.

Gerda Resch, MT (ASCP) RAC
Manager, Regulatory Affairs
Medtronic MiniMed

3/24/04
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 8 2004

Mr. Gerda Resch, RAC
Manager, Regulatory Affairs
Medtronic MiniMed
18000 Devonshire Street
Northridge, California 91325-1219

Re: K040061
Trade/Device Name: Medtronic Minimed
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: March 26, 2004
Received: March 29, 2004

Dear Ms. Resch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-5618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number:

Device Name: MicroMed 407C

Indications For Use: The Medtronic MiniMed MicroMed 407C Drug Infusion Pump is indicated for infusion of medication labeled subcutaneous and intrathecal infusion. The pump is intended for therapies at set and variable rates, for therapies including, but not limited to chemotherapy, antibiotic therapy, and controlled analgesia.

Prescription Use X
(Per 21 CFR 801. Subpart D)

or

Over-the-Counter Use _____
(Per 21 CFR807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K040061